

### **REMARKS**

The present amendment is fully responsive to the Office Action having a mailing date of April 16, 2010. After entry of this amendment, claims 1-30 are pending in the application. Claims 1 and 14 have been amended. Claims 27-30 have been canceled. Thus, claims 1-26 remain pending. No new matter has been added by this amendment, and support for the claims as rewritten may be found throughout the specification and drawings. As Applicants' remarks with respect to the Examiner's rejections are sufficient to overcome these rejections, Applicants' silence as to assertions by the Examiner in the Office Action or certain requirements that may be applicable to such rejections (e.g., whether a reference constitutes prior art, motivation to combine references, assertions as to dependent claims, etc.) is not a concession by Applicants that such assertions are accurate or such requirements have been met, and Applicants reserve the right to analyze and dispute such assertions/requirements in the future. Further, for any instances in which the Examiner took Official Notice in the Office Action, Applicants expressly do not acquiesce to the taking of Official Notice, and respectfully request that the Examiner provide an affidavit to support the Official Notice taken in the next Office Action, as required by 37 CFR 1.104(d)(2) and MPEP § 2144.03. Applicants respectfully request reconsideration of the present application in view of the following remarks.

### **Double Patenting**

The Examiner has made a provisional "double patenting" objection to claim 14 under 35 U.S.C. §101, asserting that claim 14 is a "substantial duplicate" of claim 1. Applicant respectfully disagrees. There are a number of limitations present in claim 1 that are not present in claim 14.

### **Claim Rejections - 35 U.S.C. § 102**

#### **I. The Law**

To anticipate a claim, the reference must teach every element of the claim. A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*,

814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the ... claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Claims 1, 3, 4, 8, 9, 14, 16, 17, 18, 21, 22 and 27-30 were rejected under 35 U.S.C. 102(b) as allegedly be anticipated by Siegmund (U.S. Patent No. 4,598,698). Applicants respectfully traverse the rejection.

## **II. Independent claim 1**

Independent claim 1 is directed to a biopsy system, comprising a vacuum assisted biopsy device, a first fluid source, a second fluid source, and a fluid connector. The fluid connector is positioned remotely and proximally from the biopsy device.

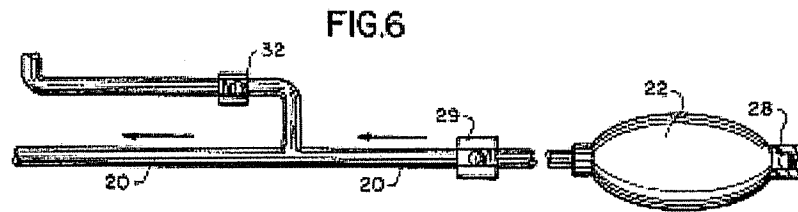
As an initial matter, no where in Siegmund is a *vacuum assisted biopsy device disclosed*. The sections referenced by the Examiner only disclose undefined “retrieval” devices with no mention of any particular features of these devices. For this reason alone, Siegmund fails to disclose all of the features of claim 1.

Further, claim 1 also requires that the fluid connector is *positioned remotely and proximally* from the biopsy device. Support for this limitation may be found in at least FIG. 1. This feature is also not taught, shown or suggested in Siegmund. Indeed, Siegmund is directed to an *endoscope* 18 having a pistol grip 19. *See e.g.*, Col. 1, lines 9-12; Col. 2, lines 32-35. The endoscope 18 includes a channel entry 26 for receiving a retrieval instrument. Col. 2, lines 41-42. Thus, the unshown retrieval instrument is inserted *into* the endoscope 18. Accordingly, Siegmund teaches *away* from claim 1, as amended, which expressly requires that the fluid connector be positioned *remotely and proximally* from the biopsy device. For at least this separate reason, claim 1 is patentably distinct from Siegmund.

The fluid connector defined by claim 1 is configured to provide the first and second fluid sources with communication with the biopsy device. The claimed fluid connector of claim 1 comprises a body member defined by a first channel and a second channel, wherein the second channel is integrally attached to the first channel such that the second channel intersects with the first channel. The first channel has a first inlet port in fluid communication with the first fluid

source and a first check valve connected to the first channel. The first check valve is positioned distally of the first inlet port and distally of the first fluid source. These features are also not shown in Siegmund.

In the office action, the Examiner identified the claimed fluid connector as endoscope 18.<sup>1</sup> The Examiner also equated the first inlet port from claim 1 as the “right-most terminus of the connector as best seen in Figure 6.” The Examiner also equated the first check valve in claim 1 as element 28. Finally, the Examiner also equated the first fluid source as bulb 22 “as best seen on the right-most side of Figure 6.” See, pg. 4 of the office action. For the Examiner’s convenience, FIG. 6 has been reproduced below.



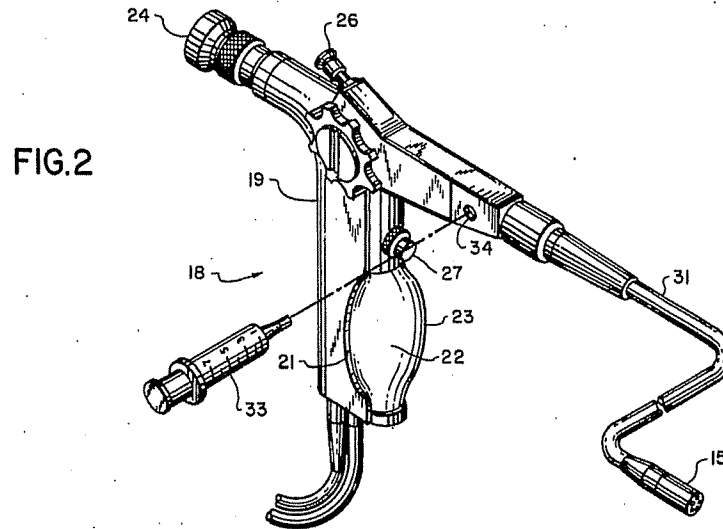
As may be seen, the check valve 28 in Siegmund is positioned *proximally* of the bulb 22. Thus, Siegmund teaches *away* from claim 1 that requires the first check valve to be positioned *distally* of the first fluid source. For at least this reason, Siegmund does not anticipate claim 1.

Further, claim 1 also requires that the first inlet port is positioned *distally* of the first fluid source. This is also not shown in Siegmund. Indeed, the first inlet necessary must be positioned proximally of the bulb 22 in Siegmund to permit air to enter into the bulb. See Col. 2, line 65-Col. 3, line 1. Accordingly, for this additional reason, claim 1 defines over Siegmund.

Finally, claim 1, as amended, requires an outlet port in fluid communication with, and *positioned proximally* of a tissue receiving opening of the vacuum assisted biopsy device. This limitation is also not shown in Siegmund. More specifically, the Examiner equated the claimed “outlet port” as “the distal outlet of combined insufflation-irrigation channel 40,” referring to FIG. 7. However, as may be seen, the “distal outlet” of the irrigation channel 40 of Siegmund is not positioned *proximally* of a tissue receiving opening of a vacuum assisted biopsy device. Indeed, Siegmund does not even describe any features of the biopsy device, and as such no tissue receiving

<sup>1</sup> As described above, Applicants disagree that an endoscope is a “fluid connector” within the context of claim 1.

opening is even discussed in Siegmund. Moreover, unlike claim 1, the unshown retrieval instrument of Siegmund is inserted *into* channel entry 26 such that a distal end of the retrieval device necessarily would extend out of channel 45. Thus the distal outlet 40 cannot be positioned *proximally* to a tissue receiving opening of a vacuum assisted biopsy device. For this additional reason, claim 1 is patentable over Siegmund.



As Siegmund fails to disclose each and every element of independent claim 1 of the subject application, independent claim 1, and dependent claims 3, 4, 6, 8 and 9 are patentable over Siegmund for at least this reason. Moreover, dependent claims 3, 4, 6, 8 and 9 each contain additional recitations that are separately patentable as well. Accordingly, withdrawal of the rejection is respectfully requested.

### III. Independent Claim 14

Independent Claim 14 recites a fluid connector comprising a body member defined by a first channel and a second channel, wherein the first channel intersects the second channel. This limitation is not shown in Siegmund.

In the office action, the Examiner identified the endoscope 18 as relating to the claimed body member of a fluid connector.<sup>2</sup> The Examiner also equated the claimed first inlet port as “the right-most terminus of the connector as best seen in Figure 6.” While the Examiner failed to identify the first channel, using the Examiner designation of the first inlet port would require conduit 20 to be the Examiner’s “first channel.” The Examiner also equated the second inlet port to be the unseen “port to atmosphere behind the check valve at 26.” And again, while the Examiner failed to identify the second channel, using the Examiner’s designation of the second inlet port would require that conduit 55 be the second channel. However, and contrary to claim 14, as amended, conduits 20 and 55 do not intersect one another. Accordingly, for at least this reason, claim 14 patentably defines over the cited prior art.

Claim 14, as amended, also recites an output port that is provided *remotely from, but in communication with* the vacuum assisted biopsy device. This limitation is also not shown in Siegmund. More specifically, in Siegmund, the endoscope 18 includes a channel entry 26 for receiving a retrieval instrument. Col. 2, lines 41-42. Thus, the unshown retrieval instrument is inserted *into* the endoscope 18. Accordingly, Siegmund teaches *away* from claim 14, as amended, which expressly requires that the fluid connector be positioned *remotely* from the biopsy device. For at least this separate reason, claim 14 is patentably distinct from Siegmund.

As Siegmund fails to disclose each and every element of independent claim 14 of the subject application, independent claim 14, and dependent claims 16-18, and 21-22 are patentable over Siegmund for at least this reason. Moreover, dependent claims 16-18 and 21-22 each contain additional recitations that are separately patentable as well. Accordingly, withdrawal of the rejection is respectfully requested.

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<sup>2</sup> As described above in connection with claim 1, Applicants disagrees that an endoscope is a “fluid connector” within the context of claim 14.

### **Claim Rejections – 35 U.S.C. § 103**

#### **I. The Law**

"To establish prima facie obviousness of a claimed invention, all the claim recitations must be taught or suggested by the prior art." *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). M.P.E.P. § 2143.03. Accord. M.P.E.P. § 706.02(j).

#### **II. Claims 2 and 15**

Claims 2 and 15 were rejected under 35 U.S.C. 103(a) as being unpatentable over Siegmund (U.S. Patent No. 4,598,698) in view of Clement (U.S. Patent No. 5,505,210). Applicants respectfully traverse the rejection.

As noted above with regard to independent claims 1 and 14, Siegmund fails to disclose a fluid connector that includes an output port that is provided *remotely from* a vacuum assisted biopsy device. However, Clement does not make up for the deficiencies in the teachings of Siegmund. Nowhere does Clement disclose, teach or suggest a fluid connector that includes an output port that is provided remotely from a vacuum assisted biopsy device as claimed by Applicants. Indeed, Clement teaches an irrigation and suction lavage assembly that includes a moveable outer cannula with a cutter. Thus, Clement teaches a biopsy device that includes a duckbill flap valve 740 *in the biopsy device*, not a separate fluid connector that is *remotely* positioned from the biopsy device.

Therefore, as neither of the references discloses a fluid connector that is *remotely* positioned from a vacuum biopsy device as positively claimed by Applicants, the combination of references fails to teach or suggest all of the elements of independent claims 1 and 14 under *In re Royka*. Accordingly, claims 2 and 15, which depend from independent claims 1 and 14 respectively, are patentable over the references for at least this reason. Moreover, dependent claims 2 and 15 each contain additional recitations that are separately patentable as well. Accordingly, withdrawal of the rejection is respectfully requested.

**III. Claims 5, 7, 12, 18, 20, and 25**

Claims 5, 7, 12, 18, 20 and 25 were rejected under 35 U.S.C. 103(a) as being unpatentable over Siegmund (U.S. Patent No. 4,598,698) in view of Miller et al. (U.S. Publication No. 2002/0082519). Applicants respectfully traverse the rejection.

As noted above with regard to independent claims 1 and 14, Siegmund fails to disclose a fluid connector that comprises a body member defined by a first channel and a second channel, wherein the first channel intersects the second channel. Nor does Siegmund disclose a fluid connector that includes a body member having an output port that is provided remotely from a vacuum assisted biopsy device. However, Miller does not make up for the deficiencies in the teachings of Siegmund. Nowhere does Miller disclose, teach or suggest a fluid connector wherein the first and second channels intersect one another. Indeed, Miller teaches a biopsy device that includes a cannula hub 312 that includes a tube fitting 375 (see FIG. 18). The cannula hub 312 provides a fluid interface for an external secondary fluid, such as a saline solution to the surgical site. *In an alternative embodiment*, Miller discloses another outer cannula hub 140. Like hub 312, cannula hub 140 includes irrigation fitting 145 for introducing fluids, like an anesthetic. *See* Paragraphs [0089]-[0090]. Thus, Miller teaches a hub that is attached directly to a biopsy device that includes an inlet port for one particular fluid source at a time. Accordingly, Miller fails to make up for the deficiencies of Siegmund.

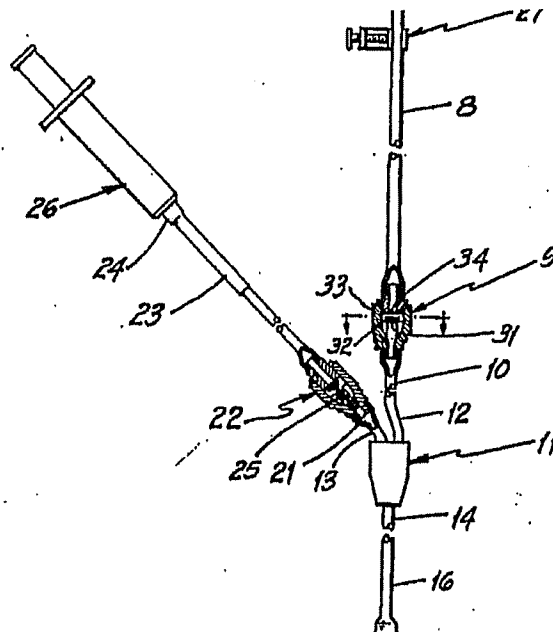
Therefore, as neither of the references discloses a separate fluid connector that is *remotely* positioned from the biopsy device as claimed by Applicants, the combination of references fails to teach or suggest all of the elements of independent claims 1 and 14 under *In re Royka*. Accordingly, claims 5, 7, 12, 18, 20 and 25, which depend from independent claims 1 and 14 respectively, are patentable over the references for at least this reason. Moreover, dependent claims 5, 7, 12, 18, 20 and 25 each contain additional recitations that are separately patentable as well.

#### IV. Claims 6, 10, 19 and 23

Claims 6, 10, 19, and 23 were rejected under 35 U.S.C. 103(a) as being unpatentable over Siegmund (U.S. Patent No. 4,598,698) in view of Moore (U.S. Patent No. 2,866,457). Applicants respectfully traverse the rejection.

As noted above with regard to independent claims 1 and 14, as set forth above in connection with the §102 rejections, Siegmund fails to disclose a fluid connector that comprises a body member defined by a first channel and a second channel, wherein the first channel intersects the second channel. Nor does Siegmund disclose a first check valve that is positioned *distally* of the first inlet port.

However, Moore does not make up for the deficiencies in the teachings of Siegmund. Indeed, Moore also fails to disclose a body member having first and second input ports, a first check valve positioned distally of the first input port as claimed by Applicants. More specifically, Moore is directed to an apparatus for administration of parenteral fluid; a portion of Figure 1 of Moore is reproduced below:



Moore discloses a connection 11, which includes a first inlet leg or inlet passage 12, a second inlet leg or passage 13, and an outlet leg or passage 14. Check valve 9 is connected by tubing 10 to



connection 11. Second leg 13 is connected by a short length of tubing 21 to a second check valve 22. See Col 1, line 61 – Col 2, line 1 and Fig. 1 of Moore.

The check valves of Moore are separated from connection 11 by tubing 10 and 21. Check valves 9 and 21 of Moore are connected to tubing 10 and 21 respectively, which are in turn connected to first leg 12 and second leg 13 respectively. Check valves 9 and 21 are spaced from connection 11 such that inlet ports of connection 11 must be positioned between connection 11 and check valves 9 and 21. Accordingly, as neither check valve of Moore is positioned *distally* of inlet ports of connection 11, Moore cannot make up for the deficiencies of Siegmund.

Therefore, as neither of the references disclose a fluid connector that comprises a body member defined by a first channel and a second channel, wherein the first channel intersects the second channel and a first check valve is positioned *distally* of the first inlet port as claimed by Applicants, the combination of references fails to teach or suggest all of the elements of independent claims 1 and 14 under *In re Royka*. Accordingly, claims 6, 10, 19, and 23, which depend from independent claims 1 and 14 respectively, are patentable over the references for at least this reason. Moreover, dependent claims 6, 10, 19, and 23 each contain additional recitations that are separately patentable as well.

**V. Claims 11, 13, 24, and 26**

Claims 11, 13, 24, and 26 were rejected under 35 U.S.C. 103(a) as being unpatentable over Siegmund (U.S. Patent No. 4,598,698) in view of Turturro et al. (U.S. Patent No. 6,331,165). Applicants respectfully traverse the rejection.

As noted above with regard to independent claims 1 and 14, Siegmund fails to disclose a fluid connector that comprises a body member defined by a first channel and a second channel, wherein the first channel intersects the second channel. Nor does Siegmund disclose a first check valve that is positioned *distally* of the first inlet port.

Turturro does not make up for the deficiencies in the teachings of Siegmund. Indeed, Turturro also fails to disclose a fluid connector including a body member having first and second input ports and a first check valve positioned distally of the first input port as claimed by Applicants. More specifically, Turturro is directed to a biopsy instrument having separate irrigation and

aspiration passageways 620 and 622, respectively. As may be seen below in FIG. 28, passageways 620 and 622 are separate passageways that do not intersect one another. Further, each passageway includes a port, irrigation port 624 and aspiration port 626. However, neither irrigation passageway 620, nor aspiration passageway 622 include a check valve positioned *distally* of either the irrigation port 624 or the aspiration port 626. Accordingly, as Turturro fails to disclose a check valve positioned *distally* of a first inlet port, Turturro cannot make up for the deficiencies of Siegmund.

Therefore, as neither of the references disclose a fluid connector that comprises a body member defined by a first channel and a second channel, wherein the first channel intersects the second channel and a first check valve is positioned *distally* of the first inlet port as claimed by Applicants, the combination of references fails to teach or suggest all of the elements of independent claims 1 and 14 under *In re Royka*. Thus, claims 11, 13, 24, and 26, which depend from independent claims 1 and 14 respectively, are patentable over the references for at least this reason. Moreover, dependent claims 11, 13, 24, and 26 each contain additional recitations that are separately patentable as well. Withdrawal of the rejection is therefore respectfully requested.

### **Conclusion**

In view of the above amendment and remarks, the pending application is in condition for allowance. If, however, there are any outstanding issues that can be resolved by telephone conference, the Examiner is earnestly encouraged to telephone the undersigned representative.

Any fee due with this response is identified in an accompanying transmittal. However, if any additional fees are due, please charge our Deposit Account No. 18-0013, under Order No. 65937-0045 from which the undersigned is authorized to draw. To the extent necessary, a petition for extension of time under 37 C.F.R. §1.136 is hereby made, the fee for which should also be charged to this Deposit Account.

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Amendment dated August 12, 2010  
After Final Office Action of April 16, 2010

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